

REMARKS

By the present amendment, Applicants amend claims 26 and 29, cancel claims 23-25 without prejudice, and add new claims 36 and 37. With this amendment, claims 26-37 are pending in this application. No additional fees are believed due; however, the Commissioner is authorized to debit deposit account no. 11-0855 for any deficiency in fees.

I. 35 U.S.C. § 102 Rejections

The Action rejects claims 23-35 as being anticipated by U.S. Patent No. 4,982,730 to Lewis, U.S. Patent No. 5,172,692 to Kulow et al., and U.S. Patent No. 5,413,550 to Castel. Applicant respectfully traverses this rejection and asks that it be withdrawn. Claims 23-25 have been cancelled without prejudice, rendering moot the Action's rejection of these claims. Claims 26 and 29 have been rewritten in independent form.

Claims 26 and 29 both recite a method for promoting wound healing by emitting ultrasonic waves that contact the wound. Claim 26 recites emitting ultrasonic waves from a transducer and reflecting at least some of the ultrasonic waves toward the wound to contact the wound and promote healing thereof.

Claim 29 recites directing ultrasonic waves emitted from a transducer toward an area offset from the axis of the transducer. None of the references relied upon by the Action teach or suggest at least independent claims 26 and 29.

A. Castel

Castel teaches an apparatus for controlling the "dosage" of ultrasonic treatment (e.g., the intensity and time of treatment) depending on the type and location of tissue to be treated and the desired effect of such treatment. Nothing in Castel teaches or suggests treating the desired tissue in any way other than by impinging the ultrasonic waves directly on the tissue. There is certainly no teaching or suggestion of reflecting ultrasonic waves toward the tissue, as recited in claim 26. Moreover, nothing in Castel teaches or suggests directly the ultrasonic waves anywhere but directly along the axis of the transducer from which they are being emitted. Castel does not teach or suggest directing ultrasonic waves toward an area offset from the axis of the transducer, as recited in claim 29.

The Action acknowledges this lack of disclosure in Castel by relying upon the principle of inherency to conclude that the "reflection of waves and the angular offset toward a wound

would be inherent in the use of the device on a patient in that both skin/tissue and bone present in the patient would inherently cause such reflections and change in direction of at least some of the ultrasonic waves.” Action, p. 2. However, the Action’s resort to the inherency doctrine is misplaced. To establish inherency, the Action must demonstrate that use of the Castel device *necessarily functions* to result in reflection of ultrasonic waves toward a wound (as recited in claim 26) and/or to direct ultrasonic waves emitted by the transducer toward an area offset from the axis of the transducer (as recited in claim 29). *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (“if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates”); *see also Ex parte Levy*, 17 U.S.P.Q. 1461, 1464 (U.S.P.Q. 1990) (“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”) (emphasis in original). “Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1990).

The Action has failed to make the requisite showing that the Castel device must necessarily function in the manner recited in claims 25 and 29. Moreover, these necessary showings are impossible to establish. The Castel device can be used to treat tissue with ultrasonic waves by emitting waves that travel along the axis of the transducer to impinge tissue that is directly in the path of such waves. Indeed, this is the most obvious intended use of the Castel device from a fair reading of Castel. Thus, no wave reflection toward a wound or directing of waves in a direction offset from the transducer axis need occur to accomplish the intended goals of the Castel device. Because the Castel device does not necessarily function to perform the methods recited in claims 26 and 29, the limitations recited in claims 26 and 29 are not inherently present in Castel and Castel does not anticipate these claims.

B. Kulow et al.

Kulow teaches a device for imparting mechanical energy impulses to a wound to reduce the swelling, redness, and inflammation of the wound. Kulow discloses substituting ultrasonic energy for the mechanical energy and touts ultrasound for the ability “to accurately select a tissue target area for treatment.” Kulow, col. 5, lines 63-68. However, Kulow provides

absolutely no disclosure of the device to be used for emitting ultrasound. Rather, the limited disclosure of Kulow at most teaches merely impinging tissue with ultrasonic waves.

As with Castel, there is absolutely no teaching or suggestion of reflecting ultrasonic waves toward the desired tissue (as recited in claim 26) or directing ultrasonic waves towards an area offset from the transducer axis (as recited in claim 29). The Action again resorts to the doctrine of inherency to supply these missing claim limitations, and again use of this doctrine is inappropriate. The complete lack of disclosure in Kulow of any device for emitting ultrasonic waves renders it impossible for the Action to establish that use of this imaginary device would necessarily function to perform the limitations recited in claims 26 and 29. Indeed, with Kulow's limited disclosure of merely impinging desired tissue with ultrasound, any ultrasonic device could certainly accomplish this function by emitting waves that travel along the axis of the transducer to impinge tissue that is directly in the path of such waves. No wave reflection toward a wound or wave path directed offset from the transducer axis must necessarily occur. Because any ultrasound device used to accomplish the disclosed goal in Kulow – impingement of ultrasonic waves on tissue – would not necessarily function to perform the methods recited in claims 26 and 29, the limitations recited in claims 26 and 29 are not inherently present in Kulow and Kulow does not anticipate these claims.

C. Lewis

Lewis teaches a device for cleaning the medullary canal and hip joint socket with liquid that is agitated with ultrasonic energy to enhance its cleaning capability. Col 1, lines 1, line 46 to col. 2, line 4. More specifically, in the Lewis device, liquid travels through a transducer 14 and emerges from delivery ports 20 on an applicator tube 16 carrying ultrasonic energy to remove unwanted debris from a bone surface. "As the liquid flows across the unwanted particles of material that cling to and is [sic] interposed between the bone and the applicator tube 16, ultrasonic energy is liberated from the liquid, shocking, vibrating, and acting upon the unwanted particles, causing the unwanted particles to be dislodged from adherence to the bone structure." Col. 5, lines 56-64. Lewis is entirely unrelated to the use of ultrasound to promote wound healing and certainly does not teach or suggest that its disclosed device promotes wound healing. Rather, as clearly reflected in its title, Lewis is directed entirely to wound *cleaning*. Nothing in Lewis teachings that the cleaning solution used in the Lewis device or the

ultrasonic energy contained therein has any benefits other than cleaning unwanted tissue and particles from bones surfaces.

Nor does the device disclosed in Lewis emit ultrasonic waves. Rather, Lewis merely teaches emission of a fluid that has been subjected to ultrasonic energy. It does not teach propagation of ultrasonic waves to contact a wound to promote healing thereof, as recited in claims 26 and 29, and thus does not anticipate these claims for at least these reasons.

Finally, even assuming, *arguendo*, that the liquid used in the Lewis device could properly be characterized as "ultrasonic waves," Lewis does not teach or suggest reflection of such liquid toward a wound. Rather, the liquid is impinged directly on the bone to remove debris thereon. Lewis thus does not anticipate claim 26 for this additional reason.

Neither Castel, Kulow, or Lewis teach or suggest the subject matter recited in independent claims 26 and 29. These claims are therefore allowable. Because none of the art relied upon by the Action anticipates independent claims 26 and 29, the art also does not anticipate claims 27 and 28, which depend from allowable claim 26, and claims 30-35, which depend from allowable claim 29. These dependent claims are therefore allowable for at least this reason.

II. Double Patenting Rejection

The Action also rejects claims 23-35 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,190,336 and claim 7 of U.S. Patent No. 5,904,659. Submitted with this Amendment and Response is a terminal disclaimer in compliance with 37 C.F.R. 1.321(c), disclaiming the terminal part of any patent granted on the above-styled application that would extend beyond the expiration date of the full statutory term of U.S. Patent Nos. 6,190,336 and 5,904,659. Applicants believe that the terminal disclaimer overcomes the Action's double patenting rejection of claims 23-35, and respectfully request withdrawal of this rejection.

III. New claims 36 and 37

Claims 36 and 37 are fully supported by the specification as originally filed at page 17, line 6 to page 18, line 15 and by Figure 3A, *inter alia*. New claim 36 recites emitting ultrasound from an annularly-shaped operative surface of a transducer. None of the art of record teaches the use of ultrasound to promote wound healing whereby the ultrasonic waves are emitted from a

transducer having an annularly-shaped operative surface. New claims 36 and 37 are therefore allowable.

CONCLUSION

Applicants respectfully submit that claims 26-37 are in condition for immediate allowance, and request early notification to that effect. If any issues remain to be resolved, the Examiner is respectfully requested to contact the undersigned at 404.815.6389 to arrange for a telephone interview prior to issuance of a final Office action.

Respectfully submitted,



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